Memo of Meeting

Date: September 13, 2000

Location: Rockville, MD

Subject: Implementation of 21 Code of Federal Regulations, Part 11; Electronic Records; Electronic Signatures

Representing the Industry Coalition on 21 CFR Part 11:

Mr. William Bradley, VP, Technical Affairs, Consumer Health Care Products Association

Mr. Christopher Allen, VP. Operations, Northern Americas Region, Bayer Corporation

Mr. Gerald McEwen, Vice President - Science, Cosmetic, Toiletry and Fragrance Association

Ms. Sia Economides, Senior Scientist, National Food Processors Association

Mr. Bernie Liebler, Director, Technology & Regulatory Affairs, Advanced Medical Technology Association

Mr. Philip Loftus, VP and Director, Worldwide IS Architecture & Technology, Glaxo Wellcome

Mr. Krishan K. Arora, PhD, VP, R&D Management Information, Pharmacia

Dr. Claudio Spiguel, VP, Commercial Information Manaement, AstraZenica (PhRMA Info. Mgmt. Liaison to the FDA)

Mr. Dave Everson, IT Management Solutions, Inc.

Mr. Donald A. Cadge, Director of Contract Operations and New Business, McNeil Consumer Healthcare

Mr. Paul ValOsten, Sr. System Support Specialist, Industrial Engineering, TEVA Pharmaceuticals USA

Frank J. Sena, PhD., Vice President/Director, Corporate Quality, Block Drug Company

Mr. Alan Goldhammer, Associate Vice President U.S. Regulatory Affairs, Pharmaceutical Research and Manufacturers of America

Representing the Food and Drug Administration, FDA Part 11 Compliance Committee:

Mr. John Taylor, Director, Office of Enforcement

Dr. Steven Solomon, Deputy Director, Office of Regional Operations

Mr. Paul J. Motise, Consumer Safety Officer, Office of Enforcement

Dr. Randy Levin, Center for Drug Evaluation and Research

Ms. Sonal Vaid, Office of Chief Counsel

Mr. Tom Chin, Consumer Safety Officer, Office of Enforcement

Mr. Brett Podoski, GHS, Center for Food Safety and Applied Nutrition

Mr. Dennis Dignan, Acting Director, DEP, Center for Food Safety and Applied Nutrition

Mr. Mark Hackman, Consumer Safety Officer, Center for Food Safety and Applied Nutrition

Mr. Stewart Crumpler, Regulatory Officer, Center for Devices and Radiological Health

Ms. Christine Nelson, Director, International Relations, Center for Devices and Radiological Health

Mr. John F. Murray, Software Engineer, Center for Devices and Radiological Health

Mr. Charles Ahn, Consumer Safety Officer, Office of Regional Operations

Mr. Jorge F. Christian, Compliance Officer, Center for Veterinary Medicine

Ms. Jennifer Thomas, Associate Director for Policy, OCBQ, Center for Biologics Evaluation and Research

The Industry Coalition requested this meeting to discuss various issues pertaining to the implementation of 21 CFR Part 11.

Dr. Solomon explained the background for the meeting, the role and tasks of the part 11 compliance committee and the framework for discussion. He noted that our comments should not be construed as formal agency policy. He explained how part 11 is being managed within FDA, the accomplishments of the committee and the task it now has to develop industry guidance. He commented that this meeting was one of several we are having with interested parties. He also explained that while we welcomed industry input we would not be collaborating with industry to co-author guidance documents. He added that the part 11 committee's primary task was to facilitate the implementation of part 11. He also commented that our dialog with the coalition is an open process, and as such, minutes of the meeting would be made public.

Mr. Taylor echoed the themes stated by Dr. Solomon and commented on the value of substantive industry feedback to producing high quality guidance and that we would follow the agency's good guidance practices in which all parties would have the opportunity to comment on draft guidance.

Dr. Solomon commented that among the guidance topics the agency is considering are validation, archiving, audit trails and scope. He added that we have already: (1) Published a compliance policy guide on part 11 enforcement (he gave copies of same to the coalition representatives); (2) prepared revisions to FDA's regulatory procedures regarding clearance of warning letters; (3) held a major public conference on implementing technical provisions of the rule; (4) developed FDA field training; and, (5) participated in numerous industry conferences.

Mr. Bradley said his group wanted to establish an ongoing constructive dialog with FDA. He noted that a representative from the Counsel for Responsible Nutrition, could not be present as originally planned. He added that the coalition has invited other organizations to participate.

Dr. Sena than gave a presentation that summarized the group's August 29, 2000 paper, "Recommendations for Achieving Compliance with the Electronic Records and Electronic Signatures Regulation." The group agreed to provide us with copies of the presentation overheads. The presentation covered the coalition's comments and concerns regarding codified definitions, timeframes for attaining compliance, risk based plans for system upgrades during a firm's normal cycle of replacements (ranging from 5 to 30 years), prioritization of remediation, software availability, long term archiving, FDA's economic assessment, and the need for uniform and clear guidance and agency expectations. He commented that the Industry Coalition had significant technical resources and expertise which would enable it to provide valuable comments for FDA to consider when the Agency drafts its guidance documents.

During the ensuing discussions, FDA representatives emphasized:

- The importance of record auditability and integrity to FDA's public health responsibilities;
- how poor electronic recordkeeping could, and in some cases has, put public health at risk;
- that while many companies realized the value of part 11, some companies were not attempting to come into compliance unless and until they received inspectional observations and warning letters from FDA;
- the difficulties in trying to define a concept like "good faith efforts" toward compliance;
- that firms were welcome to develop their own matrix of remediation priorities as long as it did not compromise FDA's ability to take regulatory action when circumstances warrant; FDA also highlighted the difficulties in publishing a general matrix given the variation in industry practices;
- how some of the coalition's concerns regarding time to compliance and availability of implementing products/services were addressed in our compliance policy guide;
- that we fully appreciated the need to expedite guidance issuance; and,
- that we don't want people to defer remediation efforts, considering that the rule is in effect and has the force of law.

Regarding the potential for a follow up dialog with the coalition, Mr. Taylor said he would call Mr. Bradley in about a month, after he had an opportunity to consult with agency officials about administrative and legal considerations. He noted that although FDA had not yet established a part 11 guidance issuance schedule, the agency is working towards issuing valuable guidance in an expeditious manner. Mr. Taylor emphasized that while FDA welcomed the Industry Coalition to submit comments and questions that they believe FDA should consider in developing guidance, it would be FDA that would actually write the guidance. Mr. Motise added that such input would add to the body of questions and comments we had already accumulated in the three years since the final rule was published.

Mr. Motise suggested that the coalition use its combined influence to persuade the software industry to accept third party audits of its software development activities so that end users could perform meaningful validation and have assurance that the software they used had structural integrity. Although the coalition said it would consider the matter, it noted that there might be potential restraint of trade issues.

We thanked the coalition and, after the usual amenities, the meeting, which lasted about two hours, ended.

Digitally signed by Paul J. Motise
cn=Paul J. Motise, ou=Office of Enforcement, o=U.S. Food and Drug Administration, c=US
Date: 2000.10.12 11:13:26 -05'00'
Reason: Authorship
Rockville, MD

DOC ID: Memo of Meeting091300_final.doc
P. Motise 9/13/00, rev 10/12/00

cc: HFA-224
HFC-300
FDA Meeting Attendees